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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/049,821

02/19/2002

Yasuyuki Suzuki

2002-0206A

2849

513 7590 04/17/2008

WENDEROTH, LIND & PONACK, L.L.P.

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WASHINGTON, DC 20006-1021

EXAMINER

PRYOR, ALTON NATHANIEL

ART UNIT

PAPER NUMBER

1616

MAIL DATE

DELIVERY MODE

04/17/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/049,821	<b>Applicant(s)</b> SUZUKI ET AL.	
	<b>Examiner</b> ALTON N. PRYOR	<b>Art Unit</b> 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 20,33 and 47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20 is/are allowed.
- 6) ☒ Claim(s) 33 is/are rejected.
- 7) ☐ Claim(s) 47 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/4/08</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

Applicant's arguments filed 12/19/08 with respect to claims have been considered but are moot in view of the new ground(s) of rejection.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 33 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a percutaneous absorption preparation comprising (S)-N-[2-(1,6,7,8-tetrahydro-2H-indeno-[5,4-b]furan-8yl)ethyl]acetamide (A = furan; X = CH<sub>2</sub>, Y = C) or (S)-N-[2-(1,6,7,8-tetrahydro-2H-indeno-[5,4-b]furan-8yl)ethyl]propionamide (A = furan; X = CH<sub>2</sub>, Y = C), does not reasonably provide enablement for a percutaneous absorption preparation comprising compounds of instant formula disclosed in claim 33 other than (S)-N-[2-(1,6,7,8-tetrahydro-2H-indeno-[5,4-b]furan-8yl)ethyl]propionamide. No results are shown for the instant formula where ring A is other than a furan ring. For example no data is provided for the formula where the A ring being oxazole or the A ring containing more than one oxygen atom or the A ring containing oxygen and sulfur. The A rings differ in polarity and functionality which would affect their activity. One would not expect for a furan to yield the same or similar activity to the oxazole ring. A similar argument can be made regarding the ring containing X and Y in claim 33. Applicants' specification examples supports X being CH<sub>2</sub>. When X is equal to NH or oxygen the polarity and functionality of the ring changes, affecting the activity of the formula. One would not expect for a pentyl or pentenyl ring to yield the same or similar activity to the nitrogen

or oxygen containing ring. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make / use the invention commensurate in scope with these claims. The compounds provided by the formula in claim 33 differ in chemical functionality and polarity as well as other chemical and physical properties. Because of this the structures encompassed in the claims may differ in activity. In fact depending upon the chemical functionality possessed by the structure an antagonistic effect could possibly result.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7,21,39,40,42,43,48,49 are no longer rejected under 35 U.S.C. 103(a) as being unpatentable over Ohkawa et al (USPN 6218429) or Ohkawa et al (USPN 6034238).

Ohkawa et al teach the formulations comprising the instant compounds such as (S)-N-[2-(1,6,7,8-tetrahydro-2H-indeno[5,4-b]furan-8-yl)ethyl]acetamide plus a surfactant including nonionic surfactants. Ohkawa teaches that the formulation can be applied in a plaster. Ohkawa teaches that the compound is administered for the treatment of sleep-awake rhythm disorders. Ohkawa does not teach the invention comprising the instant nonionic surfactant – lauric diethanolamine. See USPN '429 abstract, column 103 line 38 – column 104 line 5, column 104 line 65 – column 105 line 5. See USPN '239 abstract, column 103 line 58 – column 104 line 25, column 105 lines 17-24. It would have been obvious to replace the surfactants taught in Ohkawa

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with the instant surfactant - lauric diethanolamine. One would have been motivated to do this since the surfactants taught by Ohkawa in the prior art are used for the same purpose as the lauric diethanolamine surfactant is used for in the instant invention. The applicants provide no unobvious results for the instant lauric diethanolamine surfactant.

Response to Applicants' amendment

Claims 7,21,39,40,42,43,48,49 have been cancelled. The rejection is withdrawn.

***Claim Objection / Allowable Subject Matter***

Claim 47 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not teach or suggest the instant invention comprising (S)-N-[2-(1,6,7,8-tetrahydro-2H-indeno[5,4-b]furan-8-yl)ethyl]acetamide plus and lauric diethanolamide plus silicon dioxide.

Claim 20 is allowable. The prior art does not teach or suggest the instant invention comprising (S)-N-[2-(1,6,7,8-tetrahydro-2H-indeno[5,4-b]furan-8-yl)ethyl]acetamide plus isopropyl myristate, PEG, and lauric diethanolamide.

***Telephonic Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 571-272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alton N. Pryor/

Primary Examiner, Art Unit 1616